

REMARKS

Claims 1-10,12-27,40-48 and 52 were pending and were subjected to a Restriction and an Election of Species requirement as set forth below.

I. RESTRICTION/ELECTION REQUIREMENT

Restriction of Inventions

The Office Action states that the present claims comprise three independent inventions as follows:

Group	Claims	Drawn to:
1	1-10, 12-17, and 40-48	method for making a prognosis in a subject of enhanced recovery from an inflammatory condition or increased risk of developing an inflammatory condition by determining the genotype defined by one or more polymorphic sites in the TLR-2 nucleic acid sequence
2	18-21 and 52	kit comprising a restriction enzyme or labeled oligonucleotide; an array of nucleic acid molecules
3	22-27	a method of identifying subjects suitable for a trial testing efficacy of a candidate drug ... determining a genotype defined by polymorphic site(s) in the TLR-2 sequence and sorting the subjects...; a method for testing a drug for its efficacy in treating an inflammatory disease/condition comprising identifying subjects that are suitable for a trial and administering the candidate drug.

The Action alleges that the restriction is being made because, under PCT Rules, the groups do not relate to a single general inventive concept, and therefor lack the same or a corresponding special technical feature that would define a contribution over the prior. The basis for this position is the conclusion that the technical feature linking the Groups is “polymorphism of a genotype defined by the TLR-2 nucleic acid sequence.” The Office based its position on Lorenz *et al.*, *Infec. Immun* 68: 6398–6401. Lorenz allegedly teaches polymorphism within the TLR2 gene associated with staphylococcal infection (citing to abstract and Table 1). Thus, the polymorphism of a genotype defined by the TLR-2 nucleic acid sequence allegedly fails to make a contribution over the prior art.

Election of Species for Group I

The Office Action determined that multiple species of a single generic invention are present in the form of the list of inflammatory conditions in Claim 14 and 17. The Action indicates that claims 15 and 40-48 encompass these species and the following claims are generic to these species:

Claims 1-10, 12-14, 16-17.

The reason these species are deemed not to relate to a single general inventive concept under PCT Rules is because

the species encompass the technical feature of a type of inflammatory condition. Lorenz *et al.* (*Infection and Immunity* Nov 2000 p. 6398) teaches polymorphism within the TLR2 gene associated with staphylococcal infection (abstract and Table 1). Therefore the technical feature of a type of inflammatory condition is taught by Lorenz *et al.*

II. APPLICANTS' RESPONSE

Election of Invention

Applicants traverse the above Restriction on the basis that the it would not burdensome to examine all three indicated groups together under MPEP 806.05(c). Applicants request reconsideration of this restriction. To advance prosecution, however, Applicants elect, Group 1 (method claims 1-10, 12-17, and 40-48. and withdraw from consideration the claims that constitute Groups 2 and 3.

Election of Species

Applicants elect the following species for initial examination (referencing the section of the species election requirements indicated above:

“systemic inflammatory response syndrome” (SIRS) as the inflammatory disease or condition

The Office Action states that although Claims 15 and 40-48 encompass species of inflammatory conditions, only claims 1-10, 12-14, 16-17 are generic. Applicants' disagree and contend that in addition, claims 40-48 are generic as well, for the following reasons. Claims 40 and 46 are directed to gram positive infection. Since this condition would be expected to result in SIRS. Even if the elected inflammatory condition is SIRS, the risk genotype for SIRS would still remain a predictor of risk for gram-positive infection. Therefore these claims remain active in the case.

III. 2nd PRELIMINARY AMENDMENT

Only claims 14 and 17 are amended voluntarily in an identical manner to correct certain clerical/spelling errors. These amendments do not introduce new matter and their entry is respectfully requested.

As a result of the foregoing elections and amendments, the status of the claims is as follows:

Pending claims: 1-10,12-27,40-48 and 52.

Active claims: **1-10, 12-17 and 40-48.**

Withdrawn claims: 18-27 and 52

IV. CONCLUSION

Applicants respectfully request entry of the foregoing claims as amended, Applicants' elections and Applicants' request for reconsideration of the restriction requirement as discussed. The application is now in condition for Examination on the merits and allowance.

Respectfully submitted,

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